REMARKS

Applicants thank the Examiner for the courtesy extended in the telephonic conversation of October 23, 2003. Applicants appreciate the opportunity to discuss the pending issues in the case.

Upon entry of the amendment claims 1-11 and 21-22 will be pending in the application. Support for new claims 21 and 22 appears, e.g., in the specification at page 3, second paragraph and at page 11, first full paragraph.

Applicants submit herewith an information disclosure statement and bring to the Examiner's attention co-owned (in whole or in part) patent applications USSN 09/012,905, and 09/590,732, which also relate to the use of IL-11. These applications correspond to WO99/37322 and WO00/74707, which are enclosed as references AJ and AK in the accompanying Information Disclosure Statement.

Rejections under 35 USC § 102

Claim 1 remains rejected as anticipated by Hill et al., J. Clin. Invest. 102:115-23, 1998 ("Hill") under 35 USC § 102(a). The rejection is traversed.

The Examiner states:

> Although Hill et al. may not have fully appreciated the mechanism of treatment; the treatment itself nonetheless meets the limitations of the claim to administer IL-11 to treat GVDH. Despite the fact that applicants may have been first to characterize the effect of IL-11 on complement-mediated cytotoxicity in mammals that effect would inherently have occurred in the mammals treated by the administration prior to transplantation as described by Hill et al.

Applicants respectfully disagree that Hill inherently describes the claimed invention. Claim 1 requires identifying a mammal at risk of developing complement-mediated cytotoxicity,

and Hill fails to teach this limitation either explicitly or inherently. An "anticipating" reference must describe all of the elements and limitations of the claim in a single reference, and enable one of skill in the field of the invention to make and use the claimed invention. Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc. No. 03-1168(Fed. Cir., 2003) (citing Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1378-79 (Fed. Cir. 2001); Richardson v. Suzuki Motor Co., 868 F.2d 1226 (Fed. Cir. 1989)).

In Merck, an accused infringer contended a claim to a method of treatment of urolithiasis and inhibition of bone reabsorption by administering to a patient in need thereof an effective amount of 4-amino-1-hydroxybutane-1,1-biphosphonic acid was invalid in light of a reference ("Blum") that described pharmaceutical preparations containing the compound. In rejecting the accused infringer's argument that one of ordinary skill in the art would therefore know that the compounds would be useful for the claimed therapeutic treatment, the Federal Circuit held that "there is no suggestion of the claimed therapeutic uses in Blum; and Blum does not identify the particular compound of the claim as having superior bone resorption properties."

Applicants position is analogous to the patentee in Merck. Hill is silent about complement-mediated cytotoxicity and does not report that IL-11 has superior properties in inhibiting complement-mediated cytotoxicity. Therefore, Hill fails to describe Applicants' claimed step of identifying a mammal at risk of developing complement-mediated cytotoxicity.

Claim 6 remains rejected as anticipated under 35 USC § 102(b) by Yang et al, US Patent No. 5,700,664 ("Yang"). The rejection is traversed.

Claim 6 is drawn to a method of treating complement-mediated cytotoxicity in a mammal and requires both identifying a mammal with complement-mediated cytotoxicity and administering to the mammal a therapeutically effective amount of interleukin-11. Yang fails to teach the claimed step of identifying a mammal with complement-mediated cytotoxicity. Therefore, it does not disclose all the features of the claimed invention and does not anticipate the claimed invention.

Reconsideration and withdrawal of the rejection for anticipation are respectfully requested.

Rejections under 35 USC § 103(a)

Claims 1-11 are rejected as obvious over Hill in view of Yang. The rejection is traversed.

Claims 1, 3, and 7, from which depend the remaining claims subject to the rejection, require identifying a mammal at risk for or having a complement-mediated cytotoxicity. Although the Examiner states that Hill and Yang teach preventing and/or treating complement mediated cytotoxicity (see paragraph 8 of the Office Action). Applicants respectfully disagree for the reasons explained above in their comments addressing the rejections under 35 USC § 102. Neither reference mentions complement-mediated cytotoxicity, nor is there any suggestion in either reference of administering IL-11 to a mammal that has been identified as at risk for, or suffering from, this type of disorder.

Claims 2, 4, 5, and 7-9 specify that IL-11 be administered in doses of 1-100 μg/kg body weight for preventing or treating complement-mediated cytotoxicity. This range is not suggested by Hill or Yang. Hill describes administering IL-11 at 250μg/kg body weight for treating GVHD, while Yang teaches 1-1000μg/kg body weight for treating an immune disorder. Applicants teach in their specification that the IL-11 conferred the greatest protection against complement mediated cytolysis in vitro when provided at moderate doses (see, e.g., Examples 8 and 9 on page 22 accompanying Figure 2).

Claims 21 and 22 are patentable over Hill and Yang because neither reference discusses or suggests the use of IL-11 treat complement-mediated cytotoxicity in the context organ or tissue transplantation in a mammal.

In view of the foregoing comments, reconsideration and withdrawal of the rejection for obviousness are requested.

CONCLUSION

Applicants submit that the application is in condition for allowance and such action is respectfully requested. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

A petition for extension of time, accompanying fee, and information disclosure statement accompany this response. The Commissioner is hereby authorized to charge payment of any additional fees required in connection with the papers transmitted herewith, or credit any overpayment of same, to Deposit Account No. 50-0311 (Reference No. 22058-521).

Respectfully submitted,

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